IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Manne Satyanarayana REDDY et al. Art Unit: 1626

Application No.: 10/729,856 Examiner: N. Grazier

Filed: December 4, 2003

For: POLYMORPHIC FORMS OF DIHYDROCHLORIDE SALTS OF CETIRIZINE AND PROCESSES FOR PREPARATION THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

RESPONSE

In response to the Office Action that was mailed on December 5, 2006 for the subject application, applicants request consideration of the following traversal of the imposed restriction/election requirement.

The claims of this application were considered as pertaining to ten inventions, described as follows:

Group I including claims 1-7, and 17-23 directed to crystalline dextrorotatory or levorotatory cetirizine dihydrochloride, and pharmaceutical compositions containing them;

Group II including claims 8-12, to a process for preparing crystalline dextrorotatory cetirizine dihydrochloride;

Group III including claims 13-16, to crystalline dextrorotatory cetirizine dihydrochloride prepared by the process of claim 8 and its pharmaceutical compositions;

Group IV including claims 24-28, to a process for preparing crystalline levorotatory cetirizine dihydrochloride;

Group V including claims 29-34, 87, and 88, to crystalline levorotatory cetirizine dihydrochloride prepared by the process of claim 24, and pharmaceutical compositions containing it;

Group VI including claims 35-48 and 62-75, to amorphous dextrorotatory cetirizine dihydrochloride and pharmaceutical compositions containing it, and amorphous levorotatory cetirizine dihydrochloride and pharmaceutical compositions containing it;

Group VII including claims 49-55, to a process for preparing amorphous dextrorotatory cetirizine dihydrochloride;

Group VIII including claims 56-61, to amorphous dextrorotatory cetirizine dihydrochloride prepared by the process of claim 49 and pharmaceutical compositions containing it;

Group IX including claims 76-82, to a process for preparing amorphous levorotatory cetirizine dihydrochloride; and

Group X including claims 83-86, to amorphous levorotatory cetirizine dihydrochloride prepared by the process of claim 76, and pharmaceutical compositions containing it.

Policy for imposing restriction requirements has been established by M.P.E.P. § 803: "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." For the present application, all of the applicants' claims 1-88 relate to only a single known chemical compound: [2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl]ethoxy] acetic acid dihydrochloride (also named "cetirizine dihydrochloride"). All of claims 1-34 and 87-88 pertain to crystalline cetirizine dihydrochloride, while claims 35-86 all pertain to amorphous cetirizine dihydrochloride. To adequately examine any aspect of the invention, it will be necessary to search all of them, since the searches will be coextensive, so the burden of examining them together cannot possibly be a serious one.

In justifying the restriction requirement, distinctness was alleged incorrectly by a statement that "Inventions I and IV are unrelated products ..." and Group I was described as being drawn to a crystalline form, while Group IV is purportedly to an

amorphous product. In fact, Group I encompasses both the dextrorotatory and levorotatory forms of the crystalline compound, while Group IV claims a process for preparing the levorotatory crystals.

Further, the statement was made that "Inventions II-III, IV-V, VII-VIII, and IX-X are related as product by process and process for preparing the product," and an unsupported statement was made that "the process steps can be used to make a materially different product." Applicants believe that this position is scientifically incorrect, and no evidence is present in the record of the application to indicate otherwise.

The guidance for imposing restriction requirements in M.P.E.P. § 806.05(f) reads as follows:

> A product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process; defining the product in terms of a process by which it is made is nothing more than a permissible technique that applicant may use to define the invention.

It therefore is incumbent on the Examiner to provide something more than a conclusory statement. This is particularly true when the state of the art is such that the existence of a new polymorphic form of a chemical compound cannot be predicted, and the process that will make a new polymorphic form is not capable of prediction. See the accompanying eight-page website reprint of the article by A. Goho, "Tricky Business," *Science News*, Vol. 166, pages 122-123, August 21, 2004 for a discussion of polymorphism in drug compounds. Distinctness has not been shown, as is required by the M.P.E.P., and the restriction requirement is therefore improper.

The restriction requirement further suffers from inclusion of similar subject matter in more than one claim group. As an example, the pharmaceutical compositions of claim 7 (Group I) and claim 16 (Group III) contain crystalline dextrorotatory cetirizine dihydrochlorides that have X-ray diffraction patterns with the same peak locations. This fact could indicate a lack of consideration of the M.P.E.P. § 803 requirement that the restricted inventions must be able to support separate patents:

> Under the statute, the claims of an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to

support separate patents and they are either independent (MPEP § 802.01, § 806.06, and § 808.01) or distinct (MPEP § 806.05 - § 806.05(j)).

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

In view of the foregoing, applicants submit that no restriction can be appropriate for this application. However, if the requirement is being maintained, examination should proceed with the claims of Group I, including claims 1-7 and 17-23.

If there are any additional matters remaining for completion of this submission, please contact the undersigned.

Respectfully submitted,

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